OCT 2 3 2000

K001990

Appendix F : Summary of Safety and Effectiveness Data

I. General Information

Company :	Depilase Group Ltd. 12 James`s Squaret, London SW1 Y 4RB, United Kingdom
Contact Person :	Dr. Mario Luca Russo
Preparation Date :	06-20-00
Device Trade Name :	Depilase YAGLASE Nd:YAG Laser System and Accessories
Common Name :	Nd:YAG Pulsed Surgical Laser System
Classification Name :	Instrument, Surgical, Powered, Laser 79-GEX 21 CFR 878-48

II. Description

The Depilase YAGLASE system is based on Nd:YAG laser technology. Within the system, an optical cavity contains the Nd:YAG crystal, which is activated by means of the use of flashlamps. After the cavity, a red diode aiming beam is reflected onto a coaxial beam path using a beamsplitter assembly. The combined therapeutic and aiming beams are guided down an optical fiber delivery system to a focusing handpiece. The laser is used in non-contact mode.

The YAGLASE system is designed with 5 major sub-systems:

a) A high voltage power supply which converts and rectifies the a.c. mains current to provide regulated power for the flashlamp simmer current and main triggering pulse.

b) A cooling system consisting of an internal water flow circuit together with water-to-air heat exchanger.

c) An Nd:YAG laser rod, capable of generating optical pulses at a frequency up to 10 Hz.

d) An optical delivery system, interfacing the energy from the laser to the patient via an optical fiber and focusing handpiece.

e) The microprocessor based controller which regulates the functions of the laser and allows parameter selection by the user.

II. Intended Use

The Depilase YAGLASE Nd:YAG Laser System is indicated for the removal of unwanted hair in Fitzpatrick skin types I - V.

III. Summary of Substantial Equivalence

Depilase believes that its YAGLASE system is substantially equivalent to the Laserscope Lyra (K990718), and Altus Medical Aesthetic Nd:YAG Laser (K991798) both previously cleared for the removal of unwanted hair in Fitzpatrick skin types I - V.
They therefore have the same Intended Use as the Depilase YAGLASE Laser System..

Technologically, the predicate devices have identical characteristics to the YAGLASE, all comprising a flashlamp pumped Nd:YAG laser rod generating light at a wavelength of 1064 nm, which is subsequently delivered to the patient via an optical fiber delivery system and focusing handpiece.

The YAGLASE Laser output characteristics are very similar to those of predicate devices.

All lasers are microprocessor controlled devices.

All lasers utilize class I aiming beams which pose no hazard to the user.

All systems utilize an internal closed loop water-air heat exchanger circuit for optimal thermal control of the laser cavity.

The risk and benefits for the Depilase YAGLASE are comparable to the predicate devices when used for similar clinical applications.

It is therefore believed that there are no new questions of Safety or Effectiveness raised by the introduction of this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 23 2000

Dr. M.L. Russo
Director, Research and Development
Depilase Group, LTD
12 St. James Square
London SW1 Y 4RB,
United Kingdom

Re: K001990
Trade Name: Depilase YAGLASE Nd: YAG Laser System and Accessories
Regulatory Class: II
Product Code: GEX
Dated: September 4, 2000
Received: September 11, 2000

Dear Dr. Russo:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPENDIX G

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K001990

Device Name: **Depilase YAGLASE Nd:YAG LASER SYSTEM**

Indications For Use:

The Depilase YAGLASE Nd:YAG Laser System and Accessories ~~are intended for~~ for the removal of unwanted hair in Fitzpatrick skin types I - V.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General & Restorative Devices
510(k) Number K001990

(Division Sign-Off)
Division of
510(k) Number

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)